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【００６１】実施例９
実施例１で調製した核顆粒1.5Kgを流動層コーチング装置（FLO－1：フロイント産業製）に仕込み、ヒドロキシプロピルメチルセルロースフタレート（HPMCP）（HP－55：信越化学工業製）15gとタルク（キハラ化成製）135gをエタノール：精製水＝８：２混合溶液600gに溶解したコーチング溶液を給気温度70℃、40g／minでスプレーして水溶性被覆顆粒1620gを得た。この被膜のTMA測定装置（TMA10：セイコー電子工業製）で測定したフィルムの軟化温度は、120℃であった。得られた第１層の内側被膜コーティングに引き続き、実施例１同様に第２層腸溶コーチング（フィルムの軟化温度：30℃）と第３層被膜＊

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＊（フィルムの軟化温度：160℃）を施し、本発明のフィルムの軟化温度の差が50℃以上である３層のコーチングを有する腸溶性顆粒剤1260gを得た。
【００６２】実施例１０
実施例９で得られた顆粒剤を実施例２と同様にして打錠して腸溶性顆粒剤含有錠剤を得た。
【００６３】＜腸溶性顆粒剤の評価＞実施例９，１０について、実施例１，２と同様に腸溶性、耐打錠性を評価した結果を表７に示した。
【００６４】
【表７】

	実施例９腸溶性顆粒剤	実施例１０ 錠剤
日局試験	合格	合格
酵素活性 第１液試験前 〃　後	 ９４％ ９６％	 ９７％ ９８％

【００６５】表７に示されるように、打錠後においても十分な耐酸性を示した。
【００６６】
【発明の効果】耐打錠性のある腸溶性顆粒剤は、酵素等の酸に対する安定性の悪い薬物を、容易に錠剤化でき、また、他の配合成分との相互作用から配合することのできなかった成分を本発明の腸溶性顆粒剤とすることで容易に配合することができる。さらに、本発明をバルクに適用すれば、容易に処方検討ができ、自社での造粒顆粒化、コーチング等の煩雑な検討を省略することができる。

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(54) Title: MODIFIED STARCH COATING

(57) Abstract

Coatings for pharmaceutical dosage forms, food and confectionery tablets, seeds and granule cores are described. The coating includes a modified starch and a plasticizer optionally in combination with a secondary polymer. Also described is a coating including a modified starch and a secondary polymer optionally in combination with a plasticizer. Also described are coated pharmaceutical dosage forms, food and confectionery tablets, seeds and granule cores. Further described are cleaning, textile and feed compositions including the coated granule cores.

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MODIFIED STARCH COATING

Related Applications

This application is a continuation-in-part of U.S. Provisional Application No. 60/080,424, filed April 2, 1998, all of which is hereby incorporated herein in its entirety.

Background of the Invention

Coatings have long been used on seeds, pharmaceutical dosage forms, food or confectionery tablets, and granules such as enzymes granules to impart desirable characteristics to the final coated product. Developing coatings which have desirable properties is an ongoing source of research and development.

Thin film coating of pharmaceutical tablets allows efficient, controlled, uniform and reproducible coats. Use of multiple layers of coating, such as the polymeric undercoat, polymeric pigmented second coat and polymeric finish coat allows the preparation of very smooth glossy tablets (Ohno, U.S. Patent No. 4,001,390).

Numerous methods for pan-coating pharmaceutical tablets have been developed and are summarized in *Pharmaceutical Dosage Forms: Tablets*, Volume 3 (eds. Lieberman and Lachman, 1982, Marcel Dekker). They include sugar-coating techniques, solvent film coating, aqueous film coating, delayed release coating, and granule coating. Pulverized medicine may also be wrapped in a transparent, glossy, resistant, soluble or semi-permeable film as provided by Motoyama et al. (U.S. Patent No. 4,154,636).

Pharmaceutical tablets have been coated for a variety of reasons, including masking objectionable flavors or odors, protecting unstable tablet compositions, providing protection of the tablet through the stomach with enteric coatings, improving the appearance of the tablet or separating medicine ingredients into a core segment and coating segment.

Aspirin tablets or other tablets that are powdery, easily dissolved and friable have been treated with a variety of coatings to keep them from dissolving too soon (John et al., U.S. Patent No. 4,302,440). Also, other polymers in non-aqueous vehicles have been used to granulate tablets (Gans et al., U.S. Patent No. 3,388,041) or to coat onto tablets (Jeffries, U.S. Patent No. 3,149,040) to protect from dissolving in the stomach or to delay the drug's release. Other non-aqueous film-coating systems have been designed to be applied to a variety of tablets

containing a variety of active ingredients as illustrated by Singiser, U.S. Patent No. 3,256,111 and Brindamour, U.S. Patent No. 3,383,236. The aqueous coating processes are environmentally more safe than the non-aqueous processes, which involve the use of organic solvents in film-coating solutions. Thin film coatings, which do not alter the dissolution characteristics of the tablet, may be readily formed using aqueous film-coating processes. Unless adequately thick or insoluble coatings are used, most coatings are not capable of effectively masking the strong objectionable bitter taste of triprolidine hydrochloride or other compounds with similar properties.

Seed coating is a practice which has become widespread. It is aimed in particular at improving the germination characteristics, at providing various additives capable of intervening at any time during the growth of plants, at protecting the seeds or at imparting to the seed a shape of a size which is suitable for automatic sowing.

Granules such as enzyme-containing granules can also benefit from the presence of a coating. For example, it is desirable to coat enzyme granules in order to provide a cosmetic white or colored appearance, improve particle strength, reduce the tendency to dust in handling, reduce exposure of workers to enzymes and protect the enzyme against inactivation by moisture, oxidants and other harsh compounds. At the same time, it is important that such coatings not interact negatively with other detergent components. A coating material should also be easy to apply to the granule without excessive agglomeration or yield loss, typically by spraying onto the enzyme granules in a fluidized bed or tumbling coater.

Summary of the Invention

The present invention provides a coating including a modified starch and a plasticizer. The modified starch is preferably hydroxypropyl modified starch. The plasticizer is preferably glycerol. The coating can further comprise a secondary polymer.

The present invention further provides a coating including a modified starch and a secondary polymer. The modified starch is preferably hydroxypropyl modified starch. The secondary polymer is preferably methyl cellulose. The coating can further comprise a plasticizer.

The present invention also provides a granule including a granule core and the coating of the present invention. Also provided are cleaning compositions, textile compositions and feed compositions including these granules.

The present invention additionally provides a composition including a tablet and the coating of the present invention, a coated pharmaceutical dosage form including a pharmaceutical dosage form and the coating of the present invention, a coated seed including a seed and and the coating of the present invention.

Detailed Description of the Invention

A coating has been developed which provides the above desirable properties without any apparent negative interactions with detergent components. This coating consists of a modified starch in combination with a plasticizer and optionally a secondary polymer such as a modified cellulose. Another coating can be a modified starch in combination with a secondary polymer and optionally a plasticizer.

In general, unmodified starch or cellulose is not a good coating material. For example, generally, starch is not soluble unless gelatinized by cooking at elevated temperatures, and even then it is usually only partially soluble. Further, neither raw nor cooked starch is a good film former, nor is it easily plasticized. Unmodified cellulose is also insoluble in water.

Modified starch on its own is also not, in general, a good coating material and does not have all of the desired properties for a coating. However, it has been found that by adding a plasticizer such as glycerol, the combined modified starch/plasticizer not only has good solubility and barrier properties but is also a good coating material with excellent mechanical properties.

It has also been found that blends of modified starch and a secondary polymer such as modified cellulose have an advantage in that, for example, they combine the superior film-forming properties of modified cellulose, with the greater solubility and barrier properties of modified starch. The mechanical resilience of these films can be further improved by addition of plasticizers. A blend containing equal parts of each of these polymers, preferably with added plasticizers and pigments, has excellent film strength, good moisture barrier characteristics, and it is feasible to coat from a high solids (15-20% w/w) solution. Also, it is not tacky and can be coated onto, for example, granules or tablets without causing agglomeration.

Preferred starches have been modified in order to, for example, improve the solubility of the starch. Modified starches include starches that have been modified, for example, by acid thinning, debranching, cross-linking, instantization via jet cooking and spray drying or instantization via high temperature extrusion. Modifications to the starch include ethylation (ethyl group substitution), acetylation (acetyl group substitution), methylation (methyl group substitution), hydroxy-propyl substitution, hydroxy-ethyl substitution, carboxy-methyl substitution and hydroxypropyl methyl substitution. Examples of modified starches include:

Pure Cote (B760 and B 790)	GPC
Pure Set 765	GPC
Potato starch T1 - T5	Western Polymer
Amiogum 23	Cerestar (formerly American Maize)
Amiogum 30	Cerestar (formerly American Maize)
Amiogum 50	Cerestar (formerly American Maize)
Amerimaize 2217	Cerestar (formerly American Maize)
Amerimaize 2300	Cerestar (formerly American Maize)
Crisp Tex	Cerestar (formerly American Maize)
Batter Tex	Cerestar (formerly American Maize)
Amylean 1	Cerestar (formerly American Maize)
Ethylex gums (2015, 2035, 2040 and 2065)	AE Staley
Mira-Gel	AE Staley
Soft-Set	AE Staley
Ultra-Set	National Starch
Capsule starch	National Starch
Amylogum CLS	Avebe

Preferred modified starches are those that have hydroxypropyl substitutions. More preferably, the modified starch is Pure Cote.

Preferred plasticizers include fructose, high fructose corn syrup, glucose, lactose, maltose, galactose, raffinose/sucrose mixture, and other mono- and di-saccharide sugars, sugar alcohols such as glycerol and sorbitol, polyethylene glycols (MW 200-8000), nonionic surfactants such as linear alcohol ethoxylates and alkylphenol ethoxylates, polyols such as Neodol 23/6.5 and propylene glycol, maltodextrin, urea, triethylcitrate (TEC), citric acid, and other carboxylic acids or salts thereof.

Preferred secondary polymers include modified celluloses, polyvinyl alcohol (PVA), polyvinyl pyrrolidone (PVP) and polyacrylamide. Modified celluloses include ethylcellulose, methylcellulose, propylcellulose, hydroxypropyl cellulose, cellulose

esters and mixed esters such as: cellulose acetate, cellulose acetate butyrate (CAB), and cellulose acetate propionate (CAP).

The coating of the present invention may further comprise one or more of the following: extenders, lubricants, and pigments. Suitable pigments useful in the coating of the present invention include, but are not limited to, finely divided whiteners such as titanium dioxide or calcium carbonate or colored pigments and dyes or a combination thereof. Preferably such pigments are low residue pigments upon dissolution. Suitable extenders include sugars such as sucrose or starch hydrolysates such as maltodextrin and corn syrup solids, clays such as kaolin and bentonite and talc. Suitable lubricants include nonionic surfactants such as Neodol, tallow alcohols, fatty acids, fatty acid salts such as magnesium stearate and fatty acid esters, lecithin and waxes such as carnauba wax and beeswax.

The coating described herein may be applied by methods known to those skilled in the art of enzyme granulation, including pan-coating, fluid-bed coating, spray drying, or combinations of these techniques.

The coating of the present invention can be a final, outer coating or an inner layer such as in the case of a layered granule core.

The coating of the present invention can be used to coat, for example, pharmaceutical dosage forms, confectionery or food tablets, seeds, or granule cores to produce coated pharmaceutical dosage forms, confectionery or food tablets, seeds, or granules.

Pharmaceutical dosage forms that can be coated with the coating of the present invention include tablets, capsules, caplets and geltabs such as medicinal tablets or vitamin tablets. A large number of pharmaceutical dosage forms that can be coated with the coating of the present invention are known to those of skill in the art. Some methods for coating pharmaceutical dosage forms are described in *Pharmaceutical Dosage Forms: Tablets*, Volume 3 (eds. Lieberman and Lachman, 1982, Marcel Dekker). Similar methods can be used to coat confectionery or food tablets such as non-pareils, chewing gum balls, pieces of candy and the like.

Methods for coating seeds are well known in the art such as those described in U.S. Patent 4,879,839.

Granule cores that can be coated with the coating of the present invention include those made according to the methods described in, for example, U.S. Patent 5,324,649; U.S. Patent Application Serial No. 09/215,095; U.S. Patent Application

Serial No. 09/215,086; or U.S. Patent 4,740,469. The granule cores can be commercially available granules such as Purafect granules (Genencor International Inc., Rochester, NY) or Savinase granules (Novo Nordisk, Denmark).

The coated granule cores or granules can be used in, for example, cleaning compositions, compositions for use in treating textiles or for use in feed or food, e.g., baking.

The granules of the invention are useful in formulating various detergent compositions or personal care formulations such as shampoos or lotions. A number of known compounds are suitable surfactants useful in compositions comprising the granules of the invention. These include nonionic, anionic, cationic or zwitterionic detergents, as disclosed in US 4,404,128 to Barry J. Anderson and US 4,261,868 to Jiri Flora, et al. A suitable detergent formulation is that described in Example 7 of US Patent 5,204,015 (previously incorporated by reference). The art is familiar with the different formulations which can be used as cleaning compositions.

Granules of the invention can be included in known powdered and liquid detergents. The addition of the granules of the invention to conventional cleaning compositions does not create any special use limitation.

The present invention also relates to cleaning compositions containing the granules of the invention. The cleaning compositions may additionally contain additives which are commonly used in cleaning compositions. These can be selected from, but not limited to, bleaches, surfactants, builders, enzymes and bleach catalysts. It would be readily apparent to one of ordinary skill in the art what additives are suitable for inclusion into the compositions. The list provided herein is by no means exhaustive and should be only taken as examples of suitable additives. It will also be readily apparent to one of ordinary skill in the art to only use those additives which are compatible with the enzymes and other components in the composition, for example, surfactant.

When present, the amount of additive present in the cleaning composition is from about 0.01% to about 99.9%, preferably about 1% to about 95%, more preferably about 1% to about 80%.

The granules of the present invention can be included in animal feed as a delivery vehicle for animal feed additives such as those described in, for example, US 5,612,055; US 5,314,692; and US 5,147,642.

One aspect of the invention is a composition for the treatment of a textile that includes granules of the present invention. For example, a cellulase can be incorporated in the granule and used in a process to treat denim as is well known in the art.

The following examples are representative and not intended to be limiting.

Examples

Example 1

Seed: 25% of batch weight

Sucrose, sieved

Spray 1: Matrix layer: 41.33% of batch weight

1. Enzyme concentrate to achieve payload
2. Sucrose
3. Corn starch

Sucrose and corn starch were added directly to the UF concentrate at a 55% sucrose: 45% corn starch ratio. After calculating the amount of UF concentrate needed to achieve the desired payload, sucrose and corn starch were added to the matrix solution. The sucrose was added to the UF concentrate and mixed for 10 minutes. The corn starch was added next with moderately vigorous agitation. The corn starch was dispersed after 20-30 minutes. The matrix layer was sprayed on the sucrose seed in a fluidized bed granulator under the conditions noted in Table 1.

Spray 2: 20% of batch weight

$MgSO_4.7H_2O$

A 50% solution of the $MgSO_4.7H_2O$ (1:1 $MgSO_4.7H_2O$:water) was sprayed on the granules above in a fluidized bed granulator under the conditions noted in Table 1.

Spray 3:

Coating: 3.67% of batch weight

1. 2.5% Methylcellulose A-15
2. 2.5% Pure Cote B790
3. 6% TiO2

4. 1.0 Neodol
5. 1.67% PEG 600

This outer coating was batched as an 18% dry solids solution. Cold water was added to a vessel, then the Pure Cote B790 and TiO2 was added into the cold water. The Pure Cote and TiO2 was agitated for 10-15 minutes to aid in dispersion. After the Pure Cote and TiO2 has had time to disperse the temperature was brought up to 95°C. The temperature was kept at 95°C for 30 minutes. While the temperature remained at 95°C, the methylcellulose (MC) A-15 was added. Generally, the MC disperses at a temperature above 60°C. After the 30 minutes at 95°C, the solution was cooled down to 20°C. At 30°C, the MC A-15 dissolved. The PEG 600 and Neodol were added at this time. After 30 minutes, this solution was used in the coater. The coating was sprayed on the granules from Spray 2 in a fluidized bed granulator under the conditions noted in Table 1. The bed temperature was maintained at 20°C throughout the coater run.

TABLE 1

Running parameters:

	Spray 1	**Spray 2**	**Spray 3**	
START RATE	0.18	0.22	0.15	**Kg/min/nozzle**
END RATE	0.28	0.43	0.26	**Kg/min/nozzle**
RAMP TIME	90	30	60	**min.**
SPEC. GRAVITY	1.15	1.2	1.07	
BED TEMP	70	50	50	**°C**
ATOM. AIR PRES	5.3	3.9	5.3	**BAR**

In the following examples, materials and conditions for the seed, Spray 1 and Spray 2 are identical to those in Example 1. Conditions for Spray 3 are substantially the same as those shown in Table 1.

Example 2

Spray 3:

Coating: 14.17% of Batch Weight

1. 2.50% Methylcellulose A-15
2. 2.50% Pure Cote B790
3. 6.00% TiO2
4. 1.50% Neodol 2.3-65 T
5. 1.67% PEG 600

This outer coating was batched as an 18% dry solids solution. Cold water was added to a vessel, then the Pure Cote B790 and TiO2 was added into the cold water. The Pure Cote and TiO2 was agitated for 10-15 minutes to aid in dispersion. After the Pure Cote and TiO2 has had time to disperse the temperature was brought up to 95°C. The temperature was kept at 95°C for 30 minutes. While the temperature remained at 95°C, the methylcellulose (MC) A-15 was added. Generally, the MC disperses at a temperature above 60°C. After the 30 minutes at 95°C, the solution was cooled down to 20°C. At 30°C, the MC A-15 dissolved. The PEG 600 and Neodol were added at this time. After 30 minutes, this solution was used in the coater. The coating was sprayed on the granules from Spray 2 in a fluidized bed granulator under the conditions noted in Table 1. The bed temperature was maintained at 20°C throughout the coater run.

Example 3

Spray 3:

Coating: 13.67% of Batch Weight

1. 1.25% Methylcellulose A-15
2. 3.75% Pure Cote B790
3. 6.00% TiO2
4. 1.00% Neodol 2.3-65 T
5. 1.67% PEG 600

This outer coating was batched as an 18% dry solids solution. Cold water was added to a vessel, then the Pure Cote B790 and TiO2 was added into the cold water. The Pure Cote and TiO2 was agitated for 10-15 minutes to aid in dispersion. After the Pure Cote and TiO2 has had time to disperse the temperature was brought up to 95°C. The temperature was kept at 95°C for 30 minutes. While the temperature remained at 95°C, the methylcellulose (MC) A-15 was added. Generally, the MC disperses at a temperature above 60°C. After the 30 minutes at 95°C, the solution was cooled down to 20°C. At 30°C, the MC A-15 dissolved. The PEG 600 and Neodol were added at this time. After 30 minutes, this solution was used in the coater. The coating was sprayed on the granules from Spray 2 in a fluidized bed granulator under the conditions noted in Table 1. The bed temperature was maintained at 20°C throughout the coater run.

Example 4:

Spray 3:

Coating: 13.67% of Batch Weight

1. 2.50% Hydroxypropylmethylcellulose E-15
2. 2.50% Pure Cote B790
3. 6.00% TiO2
4. 1.00% Neodol 2.3-65 T
5. 1.67% PEG 600

This outer coating was batched as an 18% dry solids solution. Cold water was added to a vessel, then the Pure Cote B790 and TiO2 was added into the cold water. The Pure Cote and TiO2 was agitated for 10-15 minutes to aid in dispersion. After the Pure Cote and TiO2 has had time to disperse the temperature was brought up to 95°C. The temperature was kept at 95°C for 30 minutes. While the temperature remained at 95°C, the hydroxypropyl methylcellulose (HPMC) E-15 was added. Generally, the HPMC disperses at a temperature above 60°C. After the 30 minutes at 95°C, the solution was cooled down to 20°C. At 30°C, the HPMC E-15 dissolved. The PEG 600 and Neodol were added at this time. After 30 minutes, this solution was used in the coater. The coating was sprayed on the granules from Spray 2 in a fluidized bed granulator under the conditions noted in Table 1. The bed temperature was maintained at 20°C throughout the coater run.

Example 5

Spray 3:

Coating: 14.01% of Batch Weight

1. 6.16% Pure Cote B790
2. 1.56% Glycerol
3. 6.00% TiO2
4. 0.29% Sodium Laurel Sulfate

This outer coating was batched as an 30% dry solids solution. Cold water was added to a vessel, then the Pure Cote B790 and TiO2 was added into the cold water. The Pure Cote and TiO2 was agitated for 10-15 minutes to aid in dispersion. After the Pure Cote and TiO2 has had time to disperse the temperature was brought up to 95°C. The temperature was kept at 95°C for 30 minutes. While the temperature remained at 95°C, the glycerol and sodium laurel sulfate were added. After the 30 minutes at 95°C, the solution was cooled down to 20°C. The coating was sprayed on the granules from Spray 2 in a fluidized bed granulator under the conditions noted in Table 1. The bed temperature was maintained at 20°C throughout the coater run.

Example 6

Spray 3:

Coating: 30% of Batch Weight

1. 14.94% Pure Cote B790
2. 4.20% Glycerol
3. 4.20% Carnauba Wax
4. 6.00% TiO2
5. 0.66% Sodium Laurel Sulfate

This outer coating was batched as an 30% dry solids solution. Cold water was added to a vessel, then the Pure Cote B790 and TiO2 was added into the cold water. The Pure Cote and TiO2 was agitated for 10-15 minutes to aid in dispersion. After the Pure Cote and TiO2 has had time to disperse the temperature was brought up to 95°C. The temperature was kept at 95°C for 30 minutes. While the temperature remained at 95°C, the glycerol, carnauba wax and sodium laurel sulfate were added. After the 30 minutes at 95°C, the solution was cooled down to 20°C. The coating was sprayed on the granules from Spray 2 in a fluidized bed granulator

under the conditions noted in Table 1. The bed temperature was maintained at 20°C throughout the coater run.

Various other examples and modifications of the foregoing description and examples will be apparent to a person skilled in the art after reading the disclosure without departing from the spirit and scope of the invention, and it is intended that all such examples or modifications be included within the scope of the appended claims. All publications and patents referenced herein are hereby incorporated by reference in their entirety.

What is Claimed Is:

1. A coating comprising a modified starch and a plasticizer.

2. The coating of claim 1, wherein the coating further comprises a secondary polymer.

3. A coating comprising a modified starch and a secondary polymer.

4. A granule comprising a granule core and the coating of claim 1.

5. The granule of claim 4, wherein the granule core comprises an enzyme.

6. A granule comprising a granule core and the coating of claim 3.

7. The granule of claim 6, wherein the granule core comprises an enzyme.

8. A composition comprising a tablet and the coating of claim 1.

9. A composition comprising a tablet and the coating of claim 3.

10. A cleaning composition comprising the granule of claim 4.

11. A cleaning composition comprising the granule of claim 6.

12. The coating of claim 1, wherein the modified starch is a hydroxypropyl modified starch.

13. The coating of claim 3, wherein the modified starch is a hydroxypropyl modified starch.

14. A coated pharmaceutical dosage form comprising a pharmaceutical dosage form and the coating of claim 1.

15. A coated pharmaceutical dosage form comprising a pharmaceutical dosage form and the coating of claim 3.

16. A coated seed comprising a seed and the coating of claim 1.

17. A coated seed comprising a seed and the coating of claim 3.

18. A textile composition comprising the granule of claim 4.

19. A textile composition comprising the granule of claim 6.

20. A feed composition comprising the granule of claim 4.

21. A feed composition comprising the granule of claim 6.

INTERNATIONAL SEARCH REPORT

Inte ional Application No
PCT/US 99/07298

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K9/28 C11D3/386 C11D3/22 C11D17/00 A61K9/50
A23P1/08 A23K1/00 A23B9/14 C12N9/98

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 C11D A61K A23P A23K A23B C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	WO 99 32613 A (GENENCOR INT) 1 July 1999 (1999-07-01) page 19 - page 22; examples 8,10 ---	1-15
X	WO 92 11002 A (WARNER JENKINSON COMPANY) 9 July 1992 (1992-07-09) page 3, line 24 - page 4, line 13 page 6, line 27 - page 7, line 2 page 14; example 10 page 19 - page 20; example 28 ---	1-3,8,9, 14
X	DE 24 06 410 A (HENKEL & CIE GMBH) 21 August 1975 (1975-08-21) page 2, paragraph 3 - page 3, paragraph 1 page 5, paragraph 1 page 10, paragraph 2 page 14 - page 15; examples 5,11 --- -/--	1-7,10, 11

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 September 1999	15/09/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Boulois, D

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter "ional Application No
PCT/US 99/07298

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 357 846 A (GROWALD B. ET AL) 12 December 1967 (1967-12-12) column 4; example 6	1-3
X	WO 97 49762 A (HAASMAA KRISTIINA ;HEIKKILAE MAIJA ELINA (FI); POLYMER COREX KUOPI) 31 December 1997 (1997-12-31) page 3, line 8 - line 21 page 4, line 30 - page 5, line 14 page 6, line 30 - page 7, line 4 page 11 - page 12; example 4	1-3,8,9, 12-15
X	DATABASE WPI Section Ch, Week 8247 Derwent Publications Ltd., London, GB; Class D13, AN 82-02270J XP002114437 & ZA 8 106 640 A (KLOTH G G A), 2 August 1982 (1982-08-02) abstract	3,17
X	US 5 224 989 A (LIKAROVA EVA) 6 July 1993 (1993-07-06) column 3, line 21 - line 43 column 5, line 5 - line 36 column 6; examples 2,3	1-4,6,8, 9,14,15, 20,21
X	GB 2 071 708 A (ICI LTD) 23 September 1981 (1981-09-23)	1-3
A	page 9; example 2	18,19
X	US 3 989 852 A (PALMER EDWIN) 2 November 1976 (1976-11-02) column 4; example 2	1-3
X	GB 964 799 A (HERCULES POWDER COMPANY) page 2; examples 1-8	1,12
X	PSOMIADOU E ET AL: "Edible films made from natural resources;microcrystalline cellulose (MCC), methylcellulose (MC) and corn starch and polyols- -Part 2" CARBOHYDRATE POLYMERS, vol. 31, no. 4, 1 December 1996 (1996-12-01), page 193-204 XP004055900 ISSN: 0144-8617 page 194 page 201; figure 7	1-3

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 99/07298

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [ ] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. [X] Claims Nos.: –
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [X] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/ US 99/07298

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-9,12,13 (partially); 10,12 (complete)

   Modified starch coating for cleaning compositions

2. Claims: 1-9,12,13 (partially); 14,15 (complete)

   Modified starch coating for pharmaceutical dosage form

3. Claims: 1-9,12,13 (partially); 16,17 (complete)

   Modified starch coating for seed

4. Claims: 1-9,12,13 (partially); 18,19 (complete)

   Modified starch coating for textile composition

5. Claims: 1-9,12,13 (partially); 20,21 (complete)

   Modified starch coating for feed composition

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 99 07298

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-9 (partially), 10,11 (complete), 12, 13 (partially)

   Modified starch coating for cleaning compositions

2. Claims: 1-9,12,13 (partially) 14,15 (complete)

   Modified starch coating for pharmaceutical dosage form

3. Claims: 1-9,12,13 (partially) 16,17 (complete)

   Modified starch coating for seed

4. Claims: 1-9,12,13 (partially) 18,19 (complete)

   Modified starch coating for textile composition

5. Claims: 1-9,12,13 (partially) 20,21 (complete)

   Modified starch coating for feed composition

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 99 07298

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

The initial phase of the search revealed a very large number of documents relevant to the issue of novelty of claims 1-9, 12, 13. So many documents were retrieved that it is impossible to determine which parts of the claim(s) may be said to define subject-matter for which protection might legitimately be sought (Article 6 PCT). For these reasons, a meaningful search over the whole breadth of the claim(s) is impossible. Consequently, the search has been restricted to the compounds described in the description on pages 4,5 and in the examples of the present application.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.